

REMARKS

Reconsideration of this application is respectfully requested in view of the foregoing amendment and the following remarks.

Claims 1-4 were pending in this application. In this Amendment, Applicants have amended claims 1-4 and added new claims 5-19. Accordingly, claims 1-19 will be pending upon entry of this Amendment.

In the Office Action mailed March 16, 2006, under 35 U.S.C. § 102, the Examiner rejected claim 1 as being anticipated by U.S. Patent No. 6,613,064 to Rutynowski, et al. (“Rutynowski”), and claims 1-2 as being anticipated by U.S. Patent No. 4,895,147 to Bodicky, et al. (“Bodicky”). Under 35 U.S.C. § 103(a), the Examiner rejected claim 3 as being unpatentable over Bodicky in view of U.S. Patent No. 5,613,978 to Harding (“Harding”) and claim 4 as being unpatentable over Bodicky. To the extent these rejections might still be applied to claims presently pending in this application, Applicants respectfully traverse the rejections.

35 U.S.C. § 102: Claims 1-2

In the Office Action, the Examiner maintained that Rutynowski discloses every element recited in claim 1, and that Bodicky discloses every element recited in claims 1 and 2. Applicants respectfully submit, however, that claims 1 and 2 recite structural elements that are not taught nor suggested by Rutynowski and Bodicky. For example, claim 1 recites *at least one indicator* of the pre-set puncturing depth as *located in a circumferential groove* in the lower part of the sleeve. Rutynowski and Bodicky both lack an indicator that is located in a circumferential groove. In addition, claim 1 recites external cut-outs in the lower part of the sleeve, which

Rutynowski and Bodicky again both lack. These features of the present invention enable a conveniently selectable and viewable pre-set puncture depth, unlike the devices of the cited prior art references.

Rutynowski discloses a puncturing device having a sleeve 1 with an adjusting ring 3. The adjusting ring 3 regulates the depth to which the puncturing tip 8 reaches, and includes a marker 16 on its side surface. This marker 16 aligns with a scale 17 on the outer surface of sleeve 1 to indicate the puncturing depth at which the device is set. (Column 2, lines 4-7 and Figure 3.) With reference to the elements of claim 1 of the present invention, the indicating-adjusting member of claim 1 is the adjusting ring 3 of Rutynowski, and the at least one indicator of claim 1 is the marker 16 and scale 17 of Rutynowski. The depth indicator (*i.e.*, marker 16 and scale 17) of Rutynowski is therefore on the outer surface of the sleeve 1 and, contrary to claim 1 of the present invention, *is not* located in a circumferential groove of sleeve 1.

The device of Rutynowski also lacks the sleeve cut-outs recited in claim 1 of the present invention. In fact, because Rutynowski affixes its depth indicator to the outer surfaces of sleeve 1 and adjusting ring 3, Rutynowski has no need for cut-outs and indeed teaches away from such a novel solution. In the present invention, the cut-outs 33, 34, 35 in sleeve 1 enable the viewing of the at least one indicator 31, 32 located in the circumferential groove 32 of the sleeve 1. (*See, e.g.*, page 6, lines 15-19 of the present specification.) Thus, Rutynowski fails to teach or suggest at least the features of the at least one indicator located in a circumferential groove and the cut-outs, as recited in claim 1.

Bodicky discloses a lancet injector 10 that includes an elongate tubular housing 12 and a penetration depth selector 13 rotatably positioned near the distal end 22 of the housing 12. The depth selector 13 has visually readable depth markings 60 to allow the user to adjust the penetration depth of the lancet 70. (Column 4, lines 17-24.) As shown in Figure 1, these markings 60 are on the outer surface of selector 13, and align with an arrow on section 51. With reference to the elements of claim 1 of the present invention, the indicating-adjusting member of claim 1 is the penetration depth selector 13 of Bodicky, and the at least one indicator of claim 1 is the markings 60 of Bodicky. Therefore, contrary to claim 1, the at least one indicator (*i.e.*, markings 60) is located on an outer surface of the device and *is not* located in a circumferential groove of the sleeve (*i.e.*, housing 12).

The device of Bodicky also lacks the cut-outs in the lower part of the sleeve as recited in claim 1 of the present invention. In fact, because Bodicky affixes its depth indicator 60 to the outer surface of the device 10, Bodicky has no need for cut-outs in the lower part of the sleeve and indeed teaches away from such a novel solution. In contrast to claim 1, the slot 50 of Bodicky, which the Examiner apparently equates to the cut-outs recited in claim 1, allows movement of control member 48 and, because it has nothing to do with the indication of depth selection, *is not* located in the lower part of sleeve 12 where the depth selector 13 and markings 60 are located. Thus, Bodicky fails to teach or suggest at least the features of the at least one indicator located in a circumferential groove, and the cut-outs in the lower part of the sleeve, as recited in claim 1.

Applicants therefore respectfully submit that amended claim 1 is patentable over Rutynowski and Bodicky. Applicant further respectfully submits that claim 2 is also patentable over the cited prior art references due at least to its dependence on an allowable base claim.

Applicants have amended claims 1 and 2 to correct matters of form and have added new claims 5-7 dependent from claim 1 to emphasize further features that are patentable over Rutynowski and Bodicky. New claim 5 recites the at least one indicator as comprising a protrusion protruding from the indicating-adjusting member in a direction parallel to the axis of the sleeve. New claim 6 recites the lower part of the sleeve as comprising an inner wall and outer wall that define the circumferential groove. New claim 7 recites the at least one indicator as being visible through the cut-outs. Support for new claims 5-7 can be found in the present application at, for example, page 6, lines 15-18 and page 7, lines 11-13 of the specification and in Figures 1-3.

35 U.S.C. § 103: Claims 3-4

In rejecting claim 3 under § 103, the Examiner correctly noted that Bodicky does not disclose the force adjusting member recited in claim 3. For this element, the Examiner looked to the intermediate ring 50 and outer sleeve 60 of Harding. Applicants respectfully submit, however, that the intermediate ring 50 and outer sleeve 60 of Harding are limited to adjusting puncture depth and having no bearing whatsoever on puncture *force*. Harding and Bodicky therefore lack the *force* adjusting member recited in claim 3.

Harding discloses a lancet device having an adjustable tip 20 consisting of three parts: an inner sleeve 30, an intermediate cylindrical ring 50, and an outer cylindrical sleeve 60. (Column

3, lines 3-7.) The intermediate cylindrical ring 50 and outer cylindrical sleeve 60 are permanently attached to each other and rotate together as a unit relative to inner sleeve 30. (Column 3, lines 55-60.) Rotating the ring 50 and sleeve 60 changes the distance between the distal end 64 of outer sleeve 60 relative to the distal end 37 of inner sleeve 30, and thereby adjusts the *strike depth* of the needle point 72. (Column 4, lines 23-26.) Importantly, Harding is silent as to the force of the puncture, and discusses only by reference the inside workings of the device that would provide the force to the needle point 72. (Column 2, lines 54-60.)

In addition, even if the ring 50 and sleeve 60 of Harding were taken to be a force adjusting member (which they are not), the location of the ring 50 and sleeve 60 with respect to the remaining device is opposite to that of the device recited in claim 3 of the present invention. Claim 3 recites a push element mounted on one end of the sleeve, a piston mounted inside the sleeve, and a drive spring positioned between the face of the push element and the piston. The push element comprises a turnably mounted therein puncturing force adjusting member, which comprises an inwardly directed pair of oblique half-ring members pressing the piston in operation. Thus, a drive spring is between the push element and the piston, and the puncturing force adjusting member presses on the piston. This configuration enables the user to adjust the degree to which the drive spring 10 is compressed (*i.e.*, its initial biasing force as described, for example, at page 8, lines 14-17 of the specification) when the oblique half-ring members press the piston, break the wings 12, and force the piston 5, so as to deliver the puncturing tip 8 at the desired force. The shorter the oblique half-ring members are adjusted, the more drive spring 10 is compressed and the more forceful the tip 8 is propelled. In stark contrast, as discussed above,

ring 50 and sleeve 60 of Harding are part of the adjustable tip 20, having an opening 65 through which needle point 72 extends. As such, ring 50 and sleeve 60 are not part of any push element, are disposed on a side of the piston (*i.e.*, lancet body 70) opposite to where the drive spring would be, and do not press on any piston. In fact, as shown in best in Figures 7 and 8 of Harding, ring 50 and sleeve 60 do not press on anything, as the lancet body 70 contacts the inner sleeve 30 and never makes contact with the ring 50 or sleeve 60. Harding therefore fails to teach or suggest these particular aspects of the structure recited in claim 3.

In addition to the clear structural differences, because Harding relates to adjusting puncture depth, rather than force, there is no motivation to modify Bodicky with Harding to arrive at the *force* adjusting member of the invention of claim 3.

In rejecting claim 4 under § 103, the Examiner again correctly noted that Bodicky does not disclose the force adjusting member recited in claim 3, this time having inwardly directed stair shaped members. For this element, the Examiner stated that shifting the location of the stair shaped member of Bodicky from one end of the sleeve to the other would be a matter of design choice. Applicants respectfully submit, however, that such a modification would not be a design choice because the stair shaped member of Bodicky adjusts puncture depth, *not puncture force*. Therefore, it would not be obvious to move the stair shaped member to adjust puncture force. Indeed, Bodicky teaches away from such a modification by disclosing specific means for adjusting the puncture force of the device, by either retracting the control member 48 before or after pressing the device to a patient's skin (pressing it before retracting creates a vacuum that increases the puncture force). (Column 7, line 55 to column 8, line 13.) Thus, Bodicky fails to

teach or suggest the force adjusting member recited in claim 4. In contrast, the invention recited in claim 4 enables the user to adjust the degree to which the drive spring 10 is compressed (*i.e.*, its initial biasing force as described, for example, at page 8, line 26 to page 9, line 2 of the specification) when the stair shaped members press the piston 5, break the wings 12, and force the piston 5, so as to deliver the puncturing tip 8 at the desired force. The shorter the stair shaped members are adjusted, the more drive spring 10 is compressed and the more forceful the tip 8 is propelled.

Applicants have amended claims 3 and 4 to correct matters of form, and have added new claims 8-11 dependent from claims 3 and 4 to emphasize further features relative to the force adjusting member that are patentable over Bodicky and Harding. Applicants have also added new claims 12-19, which relate to the embodiments of the invention recited in claims 3 and 4, and include the patentable force adjusting features described above. Support for new claims 8-19 can be found in the present application at, for example, page 7, line 28 to page 9, line 2 and in Figures 4-7.

In view of the foregoing, all of the claims in this case are believed to be in condition for allowance. Should the Examiner have any questions or determine that any further action is desirable to place this application in even better condition for issue, the Examiner is encouraged to telephone Applicants' undersigned representative at the number listed below.

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